

Bladder Instillation Therapy: Improving Patient Outcomes Through Evidence Based Practice

DNP Final Project

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By

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### **Dedication**

I dedicate my project to my family. My husband, Eugene Perry, has been by my side throughout my journey. His love and support gave me the strength and will to continue. My children have also been supportive of my journey. I missed events that my children, Wil Perry and Kira Perry, were participating in, and they always supported me knowing that I was working hard to make the world a better place for my patients. I could not have made it through this program without their support as well as the support of my other children – Chris Fenimore, Sarah Fenimore, and Allyson Fenimore .

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### **Abstract**

Bladder instillation therapy instills intravesical medication into the bladder to treat superficial bladder cancer. Nursing staff, using a consistent standardized approach to bladder intravesical administration, can improve patient outcomes and decrease adverse events. The purpose of this Doctor of Nursing Practice (DNP) project is to improve the care of superficial bladder cancer patients receiving intravesical bladder cancer treatments by evaluating and revising an existing intravesical bladder protocol to reflect current evidence-based practice. Nursing staff were provided with an educational program regarding bladder cancer and intravesical bladder treatments. The Iowa Model of Evidence-Based Practice to Promote Quality Care framework was used to develop the project. The current bladder instillation protocol was evaluated and revised to reflect current evidence based practice. A nursing educational lecture focusing on superficial bladder cancer, risk factors, diagnosis, and treatment options was then developed and presented to twelve nursing staff members. Continuing education credits were awarded to those who attended the educational program. Patient education materials regarding bladder intravesical therapy also were evaluated and revised. A patient educational handout for Valrubicin was developed. Implementation of the revised evidence-based protocol will occur as the next step to extend the current DNP project.

In conclusion, outcomes for patients receiving bladder instillation therapy can be improved by a consistent standardized approach to their care. Nurses who are knowledgeable about the disease process and treatments of their patients can help to improve patient outcomes. Nurses who practice utilizing evidence-based protocols will promote the highest level of quality and safety for their patients. Implementation of this project will ultimately lead to more optimal care and improved patient outcomes.

## **Chapter I**

### **Introduction**

Nursing care is guided by nursing standards and protocols. Nursing standards are important as they provide, “the basis for measuring and assuring quality” (Buss, 1993, p. 238). Nursing protocols define the management of patient specific care. Protocols can be categorized as interdependent protocols, independent protocols, and teaching protocols (O’Donnell, 2005). Evidence-based nursing care is directly related to optimal patient outcomes. Standardizing care to eliminate variation among individual nurses is crucial to the delivery of safe, high quality care. In order to achieve such standardization of care, protocols are developed to support nurses to provide evidence-based nursing care using a standardized approach.

Protocols are particularly essential in the use of complex and high-risk therapies where multiple steps must be followed by nurses in the delivery of care. Nursing staff must be oriented and trained in how to follow the steps in the protocol. Intravesical bladder installation therapy is an example of such a therapy that requires use of a standardized, evidence-based protocol. The protocol for bladder instillation therapy in the urology clinic had not been updated since 2012 to reflect current evidence-based practice.

Therefore, the purpose of this project was to evaluate and revise the existing intravesical bladder protocol and provide nursing staff with an educational program regarding bladder cancer and intravesical bladder treatments. This was accomplished by developing a program to educate nursing staff on current evidence-based practice and treatments regarding bladder cancer, revising the bladder cancer intravesical protocol to support consistent use of

the evidence-based practice, and evaluating and revising the patient education handouts to reflect the evidence-based practice.

This project did not require an Institutional Review Board (IRB) review. This project was a quality improvement initiative. No human subject data collection or information was accessed. As there was no human subject data collection or informational access an IRB review was not required.

### **The Problem**

According to the National Institutes of Health (2012), a protocol is, “a detailed plan of a scientific or medical experiment, treatment, or procedure”. Established protocols are important in the hospital environment, where there is an increased risk of infection, medication errors, and errors during procedures (Institute of Medicine [IOM], 2000). The IOM reported in 2001 that, “....scientific knowledge about best care is not applied systematically or expeditiously to clinical practice” (IOM, 2001, p. 5). However, protocols are often followed based on the logic that a procedure has always been done a certain way so no changes need to be made (Jyothi, 2012). Evidence-based practice improves the quality of patient care by utilizing research to evaluate best practices (Jyothi, 2012). Evidence-based practice is the translation of research findings into best clinical practice to improve healthcare and patient outcomes (Stevens, 2001).

### **Current Practice Issues**

In the intravesical bladder instillation clinic at a large academic medical center, a protocol was previously developed to guide the administration of intravesical bladder cancer medication, but the protocol did not reflect current evidence-based nursing practice. It is unclear when the original protocol was developed. The protocol is embedded within the

overall chemotherapy administration protocol. The protocol for bladder instillation therapy was most recently revised in December 2012 by nursing education staff who had no experience with intravesical bladder instillation treatment. The protocol was revised utilizing evidence-based research that was standard practice for an operating room setting. There was no literature utilized from an ambulatory setting. The existing protocol did not reflect the current practice in the bladder instillation clinic, nor did it reflect evidence related to the therapy itself. This type of gap between the established protocol versus evidence-based practice is important to address because it can result in less than optimal patient outcomes (Thompson & Kagan, 2011).

The original orientation program was developed in 2004 by nursing staff to orient new nurses administering intravesical therapy. The bladder instillation clinic was moved to a new location with new nursing staff in 2012, and all staff were trained using the original 2004 orientation program. The orientation program was then updated shortly after the move to the new unit in 2012 by the same nursing educator that was not involved in the administration of bladder intravesical therapy or the care of bladder cancer patients.

Nursing staff currently begin orientation by reading an article entitled, *Intravesical antineoplastic therapy following transurethral resection of bladder tumors: Nursing implications from the operating room to discharge* (Washburn, 2007). New employees also review the chemotherapy and hazardous materials safe handling policies, observe and then perform one intravesical bladder instillation with each of the medications given at the hospital. The orientees must then pass a written quiz on the information learned during all of these orientation activities. They are then deemed competent to give bladder intravesical therapy independently.

A thorough understanding of disease processes and treatments is necessary for nurses to demonstrate competent technical skills and critical thought processes and to provide a high standard of care (Bashford & Shaffer, 2012). Nursing care should be both safe and effective as an end result of these abilities. Several organizations have published reports on the importance of nursing staff understanding disease process and treatments leading to an improvement in quality of care. For example, the Institute of Medicine published a report entitled, *Health Professions Education: A Bridge to Quality* (IOM, 2003). The Quality and Safety Education for Nurses (QSEN) initiative was a model developed from the IOM report in 2005. The model established guidelines based on essential components of quality and safety of patient care. The six QSEN essentials address patient centered care, teamwork and collaboration, evidence-based practice, quality improvement, safety, and informatics (Sims & Bodnar, 2012). The QSEN reports demonstrate the link between quality patient care, nursing staff who have the knowledge and skill set to safely care for their patients, and improved patient outcomes.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) develops national safety goals each year. JCAHO develops ambulatory care goals that are specific to the ambulatory care setting. In that specific care setting, national safety goals for 2014 include improved safety when administering medications (The Joint Commission [JCAHO], 2013). A competency based orientation program therefore gives nursing staff the knowledge they need to support and achieve the 2014 JCAHO safety goal, and to improve patient outcomes.



### **Role of Evidence-based Practice**

Further increasing the importance of evidence-based care with this particular patient population is the fact that medications instilled into the bladder to treat superficial bladder cancer are classified as biohazardous. Nurses are at risk for exposure when transporting, administering, and disposing of biohazardous medication waste and body fluids (Hennessy & Dynan, 2014). It is documented in literature that nurses exposed to hazardous medications have experienced adverse reproductive outcomes and increased occurrence of cancer (Polovich & Clark, 2012). Because of the risk to healthcare workers when handling these medications, personal protective equipment (PPE) is required for administration of biotoxic medications (Polovich & Clark, 2012). PPE is utilized during intravesical bladder medication administration in the bladder intravesical medication instillation clinic. The PPE utilized follows the cancer hospital's chemotherapy safe handling guidelines. However, the type of PPE utilized was not accurately reflected in the current protocol and therefore did not effectively protect nurses from the danger of exposure.

Patient educational materials are given to patients to educate them on their diagnosis and treatments. Educational materials can be presented various forms of print and media. A Healthy People 2020 objective looks at the concern of provider and patient communication clarity as well as recognizing the need for research to improve health communication (Ferguson & Pawlak, 2011). Studies have shown that when patients are educated and involved in their care, outcomes can be improved (Arnetz et al., 2010). Educational materials provide information on specific patient diagnoses, treatment options available, details on patient procedures, and a discussion of side effects that can be expected from treatment. In the bladder intravesical instillation clinic at the cancer hospital, patient educational handouts

discuss specifics of treatment and side effects that may occur. Information is given related to when the patient should call the clinic should complications occur. The patient educational material currently distributed reflected the existing bladder intravesical protocol but not the current practice in the bladder instillation clinic. Erroneous information on the current handouts was crossed out prior to providing handouts to patients. Patients commented that the crossed out information was confusing and presented an unprofessional appearance. There is a direct link between readable patient education materials and improved patient outcomes (Serxner, 2000), which further supported the need to update the patient educational materials as a part of this DNP project.

### **Rationale for Protocol Changes**

The current orientation program teaches new nursing staff how to instill bladder medications and care for bladder cancer patients but does not follow the established and the existing published protocol. The current protocol and orientation program should reflect current, evidence-based practice standards (Bashford & Shaffer, 2012). This significantly increases the likelihood that safe and effective care is provided to patients. The updated protocol also ensures that nursing personnel are adequately protected from the medication biohazards.

### **Significance of project to nursing and health care as well as relevance to the DNP**

#### **Essentials**

Nursing has a vested interest in ensuring that protocols are followed when performing procedures. The Doctor of Nursing (DNP) degree prepares nurses to lead practice changes, including the development of nursing evidence-based protocols. Nurses who are involved in applying and developing evidence-based research help to improve patient care practices

(Engvall et al., 2014). The DNP degree focuses on use of clinical research findings and its implementation in the practice setting with the goal of improving patient outcomes.

In 2006, the American Association of Colleges of Nursing (AACN) published eight essentials of doctorate education for advanced practice nursing. In 2011, The National Organization of Nurse Practitioner Faculties (NONPF) expanded on the AACN essentials. The expanded DNP nurse practitioner core curriculum includes, "...critically analyzing data and evidence for improving advanced practice nursing, translating research and other forms of knowledge to improve practice processes and outcomes, and developing new practice approaches based on the integration of research, theory, and practice knowledge" (The National Organization of Nurse Practitioner Faculties [NONPF], 2012, para. 5).

This DNP project addressed several of the DNP essentials. These Essentials included the DNP essential of scientific underpinnings for practice, organizational and systems leadership for quality improvement and systems thinking, interprofessional collaboration for improving patient and population health outcomes, and advanced nursing practice. Essential I, for this scholarly project, is Scientific Underpinnings for Practice. This essential focused on utilizing knowledge of the sciences to:

1. Critically analyze data and evidence for improving advanced nursing practice.
2. Integrate knowledge from the humanities and sciences within the context of nursing science.
3. Translate research and other forms of knowledge to improve practice processes and outcomes.

4. Develop new practice approaches based on the integration of research, theory, and practice knowledge (American Association of Colleges of Nursing [AACN], 2006).

This Essential was relevant to this scholarly project as it focused on analyzing the literature for instillation of bladder intravesical therapy medications, analyzing the current bladder intravesical therapy protocol, and revising the bladder intravesical therapy protocol in order to reflect the most current evidence-based literature to improve patient outcomes. This protocol revision focused on the current evidence, translated research and knowledge into practice, updated practice processes, and improved patient outcomes. Improving the practice process is important to nursing as it improves nursing process, which improves patient outcomes (AACN, 2006).

Essential II is Organizational and Systems Leadership for Quality Improvement and Systems Thinking that focused on quality improvement working within organizations by focusing on the needs of a population (AACN, 2006). This Essential was relevant to this project by establishing a protocol that will improve quality of patient care for bladder cancer patients receiving intravesical bladder cancer treatments, as well as improving staff competence and compliance in administering this protocol. Ensuring that the nursing staff is competent is important to ensuring patient safety and is important to upholding excellence in nursing standards.

Essential VI is Interprofessional Collaboration for Improving Patient and Population Health Outcomes. This Essential was relevant to this scholarly project as it focused on:

1. Employing effective communication and collaborative skills in the development and implementation of practice models, peer review, practice guidelines, health

policy, standards of care, and/or other scholarly products.

2. Leading interprofessional teams in the analysis of complex practice and organizational issues.
3. Employing consultative and leadership skills with intraprofessional and interprofessional teams to create change in health care and complex healthcare delivery systems (AACN, 2006).

This Essential was relevant for the project by evaluating and revising a patient protocol to reflect evidence-based practice and updating the patient educational handouts to reflect evidence-based practice. By updating the patient protocol and patient educational handouts, change in the healthcare system is created allowing for improved patient care. Quality improvement is important to improve the quality of clinical practice. Quality improvement and the improvement of clinical practice is important for nursing as a profession.

The final relevant Essential is Essential VIII: Advanced Nursing Practice. Essential VIII focuses on:

1. Design, implement, and evaluate therapeutic interventions based on nursing science and other sciences.
2. Develop and sustain therapeutic relationships and partnerships with patients (individual, family, or group) and other professionals to facilitate optimal care and patient outcomes.
3. Demonstrate advanced levels of clinical judgment, systems thinking, and accountability in designing, delivering, and evaluating evidence-based care to improve patient outcomes.

Advanced Practice Nurses assists in the education and training of nursing staff. This Essential was relevant as an educational program and updated orientation program was developed for the nursing staff. Evaluating and updating the orientation program increased the staff knowledge. These changes increased the competency of the nursing staff. This project developed and helped to sustain the partnership with the nurse practitioner and the nursing staff. It provided for optimal care for the patients and worked to improve patient outcomes. This Essential is important to the nursing staff as it improves competency in practice and supports quality and improvement initiatives.

### **DNP Project Objectives**

1. The current bladder instillation protocol will be updated to reflect evidence-based practice to improve patient outcomes. A standardized and consistent approach for instillation of bladder medications for treatment of superficial bladder cancer will be developed with evidence-based standards as the foundation.
2. Nursing knowledge will be increased related to bladder cancer and treatment options by revising and implementing an orientation program. An educational program will be developed to instruct nursing staff on bladder cancer and its causes, pathophysiology, and treatments.
3. Patient educational handouts will be evaluated and revised to reflect current practices, with the expectation that patients who receive accurate and evidence based instructions will be better supported to engage in effective self-care and benefit from improved outcomes.

Patient safety is vitally important to nursing and healthcare providers. The Hippocratic oath states to do no harm (Dinakar & Simon, 2006). Evidence-based practice and standardized

protocols help nursing staff to provide safe care and provide for better patient outcomes. The goal of this project was to update and revise the bladder instillation protocol, develop a nursing educational program to increase nursing knowledge related to bladder cancer and its treatments as part of an updated nursing orientation program, and update patient educational handouts to increase patient knowledge of the treatments they will be receiving. A literature review was completed to explore bladder cancer, instillation of bladder cancer medications, and safe handling of those medications to assist in developing a protocol and an educational program for nursing staff to ensure safe, evidence-based care.

## **Chapter II**

### **Literature Review**

Evidence-based practice for the care of ambulatory urology oncology patients is developed with research to improve care and patient outcomes. Evidence-based practice improves the quality of patient care (Dontje, 2007). An initial search of the literature was conducted to evaluate the evidence relating to bladder cancer, biohazardous agents, safety and handling of biohazardous agents, and nursing orientation and patient safety.

#### **Bladder Cancer**

Bladder cancer is a urological cancer that affects individuals all across the United States (US) and the world. Bladder cancer is the seventh most common malignancy in men and 17<sup>th</sup> most common in women. Bladder cancer patients are treated by general urologists or urologic oncology specialists. Treatments are specific to the cell type of cancer and differ according to whether the patient has superficial bladder cancer or muscle-invasive bladder cancer. Superficial bladder cancer is often treated with a transurethral resection of bladder tumor (TURBT), followed by intravesical medication instillation into the bladder.

Intravesical therapy is completed in the outpatient clinic setting. At this cancer hospital, bladder cancer patients receive their intravesical therapy treatment in the certified nurse practitioner (CNP) intravesical therapy clinic. Bladder cancer instillation therapy has been given at the cancer hospital urology clinic since the 1980s and in the current clinic location since November 2012. The clinic is managed by the CNP and staffed with two to three nurses and a patient care associate. Nursing staff need to be well versed on the treatments that they are administering, the side effects of those treatments, and side effects that can require revisions to the treatment being given. A protocol should be in place to guide



administration of intravesical bladder therapy (Mellinger, Skinker, Sears, Gardner, & Shult, 2010).

Bladder cancer patients can typically present with one or several complaints, including gross painless hematuria or microhematuria noted on urinalysis (Jones & Larchian, 2012). Patients will often see their primary care physician first. A urine culture and urinalysis are obtained, commonly revealing a negative culture. Primary care providers should then refer patients to a urologist to evaluate the hematuria.

Subsequent evaluation typically includes a cystoscopy to identify any abnormalities within the patient's bladder. A cystoscopy is a procedure in which the urologist inserts a telescope (cystoscope) with a small camera attached into the bladder. The urologist is able to visualize the inside of the bladder for the presence of any tumors or abnormalities. A transurethral resection of the bladder tumor is then performed in the operating room (OR) if a bladder mass is identified (Jones & Larchian, 2012). Depending on the cell type of bladder cancer identified, as well as depth of tumor invasion, staging studies, and other pathologic variables, a decision is made on what type of treatment is needed.

Superficial bladder cancer, also called non-invasive bladder cancer, is further categorized by stage. Bladder cancer staging is the categorization of cancer cell aggressiveness and extent of cancer spread. There are two types of staging – clinical and pathological staging. Clinical staging is the provider's assessment of how far the cancer has spread based on exam, laboratory studies, and imaging studies (American Cancer Society, 2015). Pathological staging is based on examination of the cancer cells underneath the microscope by a pathologist who determines aggressiveness of the cells and the extent of invasion (Urology Care Foundation, 2014). Pathological bladder cancer staging is reported as

tumor staging also known as T staging (Urology Care Foundation, 2014). Pathological stage Ta is the most common type of superficial bladder cancer (Washington University Department of Surgery, 2011). The tumor looks like a cauliflower configuration in the bladder and does not grow or invade into other layers in the bladder. These tumors are treated with TURBT and surveillance or alternately with TURBT and bladder instillation therapy to reduce recurrence risk.

Carcinoma in situ (CIS) is another form of superficial bladder cancer. It is seen as a red, velvety patch in the bladder that develops on the surface wall of the bladder. It is a flat, but high grade, non-invasive cancer. It can develop into muscle invasive disease if left untreated. T1 stage bladder cancers have extended through lamina propria. The lamina propria is the layer of the bladder under the epithelium or mucosa, separating the bladder lining from the deeper muscle layers. The tumors may, if left untreated, develop the potential to invade into the muscularis propria consistent with muscle-invasive disease.

Muscle invasive bladder cancers are not typically fully controlled by transurethral resection and often require radical cystectomy or chemotherapy and radiation therapy for definitive treatment. For patients with superficial disease or patients with T1 disease who are selected for bladder instillation therapy, weekly sessions of instillation are undertaken. BCG is typically six weekly instillations. Maintenance treatments have been shown to decrease risk of recurrence in comparison to induction therapy alone (Lamm, McGee, & Hale, 2005). This is typically given for three weekly instillations.

Intravesical bladder cancer instillation is the instillation of medication directly into the bladder to affect the cells lining the bladder (American Cancer Society, 2014), and is a current standard of treatment for these patients. A number of different medications can be instilled

into the bladder for cancer treatment. Evidence shows that BCG is the most effective intravesical immunotherapy for treating early-stage bladder cancer (American Cancer Society, 2014). It is thought that BCG works by stimulating the body's own immune system, thereby stimulating an immune reaction to the bladder cancer cells as well. Treatment is started approximately four weeks after the patient's TURBT and is given weekly for a total of six weeks. An induction course of BCG is the initial six-week course that a patient is given for treatment. Maintenance doses can be given every three to six months for three weeks to prevent recurrence.

Chemotherapy agents that are given IV can also be given intravesically into the bladder for treatment. Chemotherapy agents used for this type of treatment include Mitomycin C (MMC), Valrubicin (Valstar), Doxorubicin, and Thiotepa. MMC is the agent that is more commonly used over the other agents. MMC is often instilled into the bladder directly after a TURB while the patient is still in the OR. It then can also be instilled into the bladder weekly for six consecutive weeks. Valrubicin (Valstar) is another chemotherapy agent that can be utilized weekly for six consecutive weeks. Valrubicin was approved by the Federal Drug Administration (FDA) for patients that have BCG resistant CIS and are not candidates for radical cystectomy (Cookson et al., 2014).

Intravesical bladder medications can cause side effects when instilled into the bladder. The medications can cause irritative voiding symptoms of urinary frequency, urgency, and dysuria. BCG can also have immunology side effects including fever, chills, flu like symptoms, and joint aches. The patients fill out a Quantitative Symptom Score Sheet (QSS) every day during treatment starting with the day of treatment. Patient treatment decisions are made based on the side effects the patients are having.

<b>Table 2: Side effects of treatment and estimated probabilities of occurrence</b>				
<b>Intravesical Agent</b>				
<b>Side Effects</b>	<b>BCG</b>	<b>Mitomycin C</b>	<b>Thiotepa</b>	<b>Doxorubicin</b>
Frequent urination	63%	42%	11%	27%
Painful urination	75%	35%	30%	20%
Flu-like symptoms	24%	20%	11%	7%
Fever or chills	27%	3%	4%	4%
Systemic infections	4%	Not available	0.3%	Not available
Skin rash	6%	13%	2%	2%
Suppression of bone marrow activity	1%	2%	13%	0.8%

(American Urological Association [AUA], 2014)

Monitoring of patient side effects is very important, as treatment decisions are made based on how the patient is tolerating the therapy. The medications instilled into the patient's bladder for treatment are considered biohazardous and need to be handled in a way that minimizes effects to the patients and limits exposure for the staff. The therapy must be administered accurately, safely, and consistently to promote quality care.

### **Biohazardous Agents**

BCG is a live culture preparation of the Bacillus of Calmette and Guerin strain of *Mycobacterium bovis* (Merck & Co, 2009). Currently, this hospital uses TICE® BCG, which is manufactured by Merck. According to Merck, (2009), BCG contains live mycobacteria and should be prepared and handled using aseptic technique as BCG infections have been reported in health care workers preparing BCG for administration. Merck (2009) further recommends that TICE® BCG should be handled and disposed of as a biohazardous substance. The nursing staff currently follows the hazardous drugs safe handling policy for handling of the BCG. Instillation of the BCG, including handling and disposing of the materials, follows a protocol that was developed in December 2012 that has not been updated since that time.

Another agent used in the treatment of these patients is Mitomycin C (MMC).

Mitomycin C is an antineoplastic agent and is classified as an antitumor antibiotic. It acts as an alkylating agent stopping cells from making DNA, which results in cell death.

Biohazardous medications and should be administered and disposed of in accordance with practices that protect the health care worker (Polovich, 2004). The nurses in the bladder instillation clinic should follow the safe handling practices outlined in the hazardous drugs safe handling policy of this cancer hospital. The most current instillation protocol for Mitomycin C, which includes handling and disposing of supplies, was developed in December 2012 and had not been updated since that time.

The use of Interferon acts as a glycoprotein that mediates a host's immune system. Interferon increases antibody responsiveness and stimulates killer cells (Brassell & Kamat, 2006). Interferon alpha 2b is sometimes used in combination with BCG and can be highly effective in the treatment of superficial bladder cancer (Lamm et al., 2005). Combination therapy is given for a 6-week induction course. Interferon A should be handled by nursing staff following the Cancer Hospital's safe handling policy of biohazard agents. There is an older protocol for instillation of BCG instillation but there is no protocol for instillation of BCG in combination with Interferon A.

Another agent that may be used is Valrubicin, an anthracycline antibiotic. It prevents protein synthesis by binding DNP base pairs and inhibits topoisomerase II (Brassell & Kamat, 2006). Valrubicin is given for patients who have failed BCG therapy and are not good surgical candidates for cystectomy. Valrubicin is a biohazardous agent and should be handled and discarded following appropriate protocols. The nursing staff are instructed to follow the

cancer hospital's safe handling guidelines of biohazard agents for handling and disposal, but there is a need for a separate defined protocol for intravesical instillation of Valrubicin.

### **Safety in Handling and Administration of Biohazardous Agents**

Safe administration and handling are important to protect health care workers from exposure to biohazardous agents. Hazardous drugs are categorized by exhibiting specific characteristics. Drugs exhibiting one or more of the following effects are classified as hazardous: carcinogenicity, teratogenicity, genotoxicity, reproductive toxicity, or organ toxicity at low doses (American Society of Health System Pharmacists, 2006). Health care providers can be exposed to hazardous agents during preparation, handling, administration, and disposal of the agents. Such exposure to biohazardous agents has been linked to long term and acute health effects including reproductive effects and increased incidence of cancer (Polovich & Martin, 2011). For example, leukemia and other cancers were linked to several chemotherapy agents in the 1970's (Thomas & McDiarmid, 2006).

Cytotoxic findings led to the consideration of exposure causing risk of cancer to the healthcare workers that handled them (Polovich, 2004). A controlled study was done that noted toxins in the urine of patients and healthcare workers that were exposed to chemotherapy drugs (National Institute for Occupational Safety and Health [NIOSH], 2004). Beginning in the 1980's, guidelines were published with recommendations to reduce the risk of exposure to healthcare workers when handling biohazards drugs.

The first such guidelines came from the American Society of Hospital Pharmacists (Polovich & Martin, 2011). The organization published guidelines in 1985 detailing safe handling precautions for healthcare workers to decrease exposure to potentially unsafe medications (ASHP, 1985). In 1986, the Occupational Safety and Health Administration

(OSHA) developed guidelines addressing the issue of safe handling of biohazardous drugs. In 1988, the Oncology Nursing Society published recommendations for safe handling of biohazardous drugs (Polovich, 2005).

The Occupational Safety and Health Act of 1970 established the National Institute for Occupational Safety and Health (NIOSH) (Centers for Disease Control [CDC], 2013).

NIOSH is a federal agency that utilizes evidence-based research to make recommendations for worker safety. NIOSH collaborated with the Occupational Safety and Health Administration (OSHA) and is part of the CDC (CDC, 2013). NIOSH supports research to improve employee safety in the workplace (CDC, 2013).

NIOSH publishes recommendations focused on health workers' occupational hazards in handling cytotoxic drugs (National Institute for Occupational Safety and Health [NIOSH], 2004). NIOSH continues to update these guidelines to protect healthcare workers from occupational exposure. Since the NIOSH alert was published in 2004, the organization has updated their list of biohazardous drugs in 2010, 2012, and 2014. BCG, Mitomycin C, and Valrubicin are included in the NIOSH list of biohazardous drugs, and such updates must be included in the processes and practices related to their implementation.

NIOSH recently published a new *Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care* (NIOSH, 2014). The recommendations were given to limit the exposure during hazardous drug preparation and handling. Within the report, NIOSH provided a list of biohazardous drugs that healthcare workers should take precautions when handling. The purpose of this report was to increase awareness of healthcare workers and their agencies in the hazards related to handling of biotoxic medications (Polovich & Martin, 2011).

**Nursing Orientation and Patient Safety**

Nursing professionals are responsible for having the knowledge to provide safe care to patients. Nurses must ensure that safe practices are followed to decrease the risk of harm to patients as well as to themselves. This is particularly true in the administration of certain therapies that can be toxic, such as chemotherapeutic agents. Orientation and education are both necessary to provide training to communicate appropriate protocol and procedures to nursing staff (Mellinger, Skinker, Sears, Gardner, & Shult, 2010).

In summary, bladder instillation medications are biohazardous, and patients and their nurses can be seriously harmed if there is a lack of compliance with handling procedures (NIOSH, 2014). Proper protocols should be followed to ensure safety of both the nursing staff and patients during administration (NIOSH, 2014). Without proper training and evidence based protocols to guide the administration, harm can come to patients in the development of infections, and to nurses in the development of cancers and other detrimental health effects (Polovich & Martin, 2011). The outpatient clinic has the responsibility for ensuring the safety of the nursing staff and patients.



### **Chapter III Methods**

#### **Project Design**

Nursing protocols allow for application of nursing knowledge in a standardized approach in order to improve patient outcomes. This project was guided by the Iowa Model of Evidence-Based Practice to Promote Quality Care theoretical model (Titler et al., 2001). This project utilized a quality improvement design to improve clinical practice. The setting was in the intravesical bladder instillation clinic at a large Midwestern Cancer Hospital. The project evaluated and revised the current Intravesical Bladder Installation Protocol (see Appendix A). Development of the protocol followed guidelines set by this large urban Midwestern Cancer Hospital. It is anticipated that the protocol will be submitted for approval to the institution's Policy and Procedure Committee after the completion of this student's DNP clinical immersion experience.

The orientation process for new nursing staff was also evaluated and revised to provide updated and evidence based knowledge to those nurses regarding intravesical bladder instillation therapy. A formal presentation was presented to educate nurses on bladder cancer and the treatments available. The revised orientation program was designed as part of this DNP project and will be implemented after completion of the DNP program. The current patient educational handout (see Appendix B) was also evaluated and revised to reflect the change in nursing protocol.

#### **Sample**

The sample for this project was the nursing staff who work in the bladder intravesical instillation clinic. The nursing staff is currently comprised of Registered Nurses (RNs) who are assigned to that clinic. The RNs currently working in the clinic have been on staff there,

on average, for the past year, so represent a relatively new nursing employee group for whom the updated education could be especially beneficial. There are patient care associates who work in the clinic but they were not a focus of this project as they are not directly involved in implementing bladder installation therapy.

### **Process**

In order to develop a consistent approach to bladder instillation therapy to improve patient outcomes, a process plan was developed. An outline of steps to the project was developed to ensure that all facets of the plan were addressed. This plan included development of an evidence-based process and protocol for the administration of bladder instillation therapy, and detailing the standard nursing care before, during and after the procedure.

### **Step One:**

Intravesical bladder cancer instillation protocols are currently embedded in the chemotherapy administration protocol within the institution in which this DNP project was implemented. The first step evaluated the current protocol and compared it to the current practice in the bladder intravesical therapy instillation clinic. Differences between the protocol and actual practice, including safety practices, were evaluated. The protocol was then updated to reflect current evidence-based practice and must be submitted and approved by the cancer hospital prior to implementation. The implementation process will be initiated after completion of the DNP program. Future steps will include completion of the approval process and implementation of the protocol changes in the bladder intravesical therapy clinic.

**Step Two:**

The orientation program for the nursing staff in the bladder intravesical instillation clinic was evaluated and compared to the revised protocol. Updates were made to improve nursing knowledge of bladder cancer and intravesical treatment options for superficial bladder cancer. The orientation process was updated to reflect the new protocol. An educational program was developed and presented to the nursing staff to educate them on superficial bladder cancer and available treatment options. Information was not included regarding the revised protocol, as it is not yet approved by nursing administration. Education regarding the revised protocol will be presented later after the protocol has been approved by the protocol committee. Continuing education credits were awarded to staff that attend the program, and it will become a component of the annual competency testing that is mandatory for all nurses on the unit.

**Step Three:**

The current patient education packet was evaluated and compared to the new protocol. Updates were made to revise the educational material to reflect the newly revised intravesical protocol. The revised patient educational material was submitted to the patient education department at the cancer hospital for approval with the goal of implementation after completion of this project.

**Instruments**

A nursing evaluation form was utilized to measure response to the nursing educational program that will be presented to nursing staff. The evaluation form will measure the quality of the educational program, knowledge gained from the educational program, and overall

response to the educational program. The evaluation form will be utilized to evaluate any future needs/improvements to the course in the future.

**Data Analysis Plan**

This project will make a difference in the clinical practice in the bladder instillation clinic. Standardized information provided to all new nurses as well as current nursing staff ensures that the rationale for care of these patients is at the foundation of their preparation for work in this clinic. Annual competency testing will measure retention of knowledge about the updated protocol in the form of a written quiz.

## **Chapter IV**

### **Findings**

#### **Results**

The purpose of this project was to evaluate and revise the existing intravesical therapy protocol for bladder cancer and to provide nursing staff with an education program regarding bladder cancer and intravesical bladder treatments. The intravesical therapy protocol was evaluated and found to have multiple discrepancies between the protocol and actual nursing practice. Discrepancies noted ranged from the type of urethral catheter used, to how the procedure is done, to post-procedure patient education instructions. The changes were made to align the protocol with evidence-based practice standards.

#### **Intravesicular Bladder Instillation Protocol**

The current bladder intravesicular therapy protocol is embedded in the Chemotherapeutic/Biotherapeutic Agents protocol. When a search for this protocol is attempted under search terms specific to intravesical instillation therapy, the protocol is not found due to the protocol being a part of the chemotherapy infusion protocol. Unless one specifically knows that bladder instillation therapy is embedded into the chemotherapy administration protocol, it cannot be easily accessed. The protocol is divided into the following topics: supplies, patient education, procedure specific assessment and interventions, and post procedure complication signs and symptoms. Implementations are listed under each topic and detail the procedure. The current protocol was based on published findings related to bladder intravesical therapy that is administered in the operating room and not in the ambulatory setting.

In a review of the literature, it was found that there is little research pertaining to this therapy in the ambulatory setting. Protocols from other organizations were reviewed from

both within and outside of the United States. Stamford Hospital developed a protocol outlining intravesical instillation and administration of both BCG and MMC (Thompson, 2011). In their protocol, it is noted that it is important to provide the proper safety protection for personnel administering the medications (Thompson, 2011). In a review of Western Australia's bladder instillation protocol, the authors noted that any practitioner giving intravesical therapy needs appropriate training and assessment (Washington Cancer and Palliative Care Network, 2010). After a thorough review of the literature as well as current national standards of practice for this procedure, the following changes were made to the intravesical therapy for bladder cancer protocol (see Appendix A):

- Supplies:
  - “Foley catheter kit” changed to: *urethral catheter kit*.
  - “14 or 16 french-foley catheter” changed to: *Coude or red rubber catheter*.
  - “Biohazard bag” changed to: *Biohazard trash bag (Yellow or Red depending on medication instilled)* (The Ohio State University Wexner Medical Center [OSUMC], 2014).
- Patient Education:
  - “Explain to patient – the procedure will be done once per week for six weeks in a row” changed to: *Explain to patient – the procedure will be done once per week for either three or six weeks in a row* (Lamm et al., 2000).
  - “Explain to patient not to urinate for 2 hours after the procedure” changed to: *Explain to patient not to urinate for 2 hours after the procedure. (Intravesical medication needs to remain in the bladder for 2 hours and not more than 3 hours)* (Farah, Ghanem, & Amr, 2014).

- “1 cup of household bleach should be added to the toilet and let it stand for 15 minutes prior to flushing the toilet” changed to: *one cup of household bleach should be added to the toilet and let it stand for 15 minutes prior to flushing the toilet twice with the toilet lid down* (Merck & Co, 2009).
- “Instruct patient to call the hospital operator and ask for the resident on call or their physician or go to the ER” changed to: *If patient develops a fever over 101.5 seek medical attention if does not resolve with Tylenol or NSAIDs* (Merck & Co, 2009).
- “PPE (mask, gloves and gown) will be worn from start to finish of procedure” changed to: *PPE (mask, gloves {double gloved with chemotherapy and sterile gloves}, goggles, and gown) will be worn from start to finish of procedure* (Polovich, 2004).
- “Mitomycin C: Instill medicine into Foley catheter and allow contents to go into bladder by gravity. Deflate Foley balloon and remove Foley catheter” changed to: *Instill medicine into catheter by slow pushing the medication into catheter with a toomey catheter tip syringe.*
- “BCG: Squeeze tubing chamber to allow medicine to drain part way into the chamber” changed to: *squeeze bottle to start flow of medicine* (The Ohio State University James Cancer Hospital [The James], 2012).

Changes to departmental policies and procedures need to go through several steps prior to approval. First, the changes are identified by an individual or group. The proposed changes are noted and then must be submitted and authorized by the department director and administrator. The department director ensures that implementation, communication and

enforcement of the policies and procedures occurs (The Ohio State University Wexner Medical Center [OSUMC], 1993).

For the newly revised bladder intravesical instillation protocol, the proposed changes have been identified and are awaiting submission to the department director and administrator. The changes to the bladder intravesical installation protocol led to the need to update the patient education handouts.

### **Patient Education**

BCG and Mitomycin C each have a patient education handout. The Mitomycin C patient education handout was last updated on May 20, 2011. The BCG patient education handout was last updated on April 3, 2013. There is no patient education handout for Valrubicin.

### ***BCG***

The BCG patient education handout is entitled, “BCG Therapy – Intravesical Treatment for Bladder Cancer”. There were minimal changes to this document. A sentence was added stating that BCG can alternately be given once a week for three weeks if receiving maintenance therapy. A revision was made to the following statement: “If you have a temperature greater than 101 degrees Fahrenheit, go to the nearest Emergency Room,” which then became “If you have a temperature greater than 101.5 degrees seek medical treatment” (Merck & Co, 2009) (see Appendix B).

### ***Mitomycin C***

The Mitomycin C patient education handout is entitled, “Mitomycin-C Therapy Intravesical Treatment for Bladder Cancer”. This document has not been updated in almost four years. The Mitomycin C patient education document had more extensive changes. The



handout noted that for male patients, “A clamp will be placed on your penis to make sure the Lidocaine does not drain out. The clamp will be removed after 10 minutes” (OSUMC, 2011, para. 12). This sentence was deleted as this practice is not routinely done in the clinic.

Additional information was added to paragraph 15, to read, “After Mitomycin-C is given, the catheter is removed. The Mitomycin-C will remain in the bladder” (OSUMC, 2011, para. 15). An additional sentence was added as follows: “You will need to lie flat for 15 minutes after the procedure. After lying flat for 15 minutes, you will be able to get up, wash your genital area, and get dressed” (Lamm, McGee, & Hale, 2005).

The following sentence was changed from, “write down how long you held the medicine in your bladder” to “write down how long you held the medicine in your bladder on the bottom of your Quantitative Symptom Score Sheet”. The following two sentences were deleted – “Do not flush the toilet when you finish urinating” and “Before you flush, you must first pour one cup of bleach into the toilet, and let it stand for 15 minutes. You may then flush the toilet”. The following sentence was added instead: “Flush the toilet twice with the lid down” (OSUMC, 2014).

A notation was also added that the medication can cause a blue tint to urine that the patient may notice when urinating and the color change is normal. The last sentence of the document was changed from “If you have a temperature greater than 101 degrees go to the nearest Emergency Room” to “If you have a temperature greater than 101.5 seek medical attention” (See Appendix C).

### ***Valrubicin***

As a part of this DNP project, a patient education handout entitled, “Valrubicin Therapy Intravesical Treatment for Bladder Cancer” was developed. Valrubicin is a

chemotherapy with similar instillation procedure as well as similar side effects and precautions. The Mitomycin C patient education handout was used as a template. References to Mitomycin C were changed to Valrubicin. A notation was made that the Valrubicin can cause a red tint to urine as the medication is red in color and that the color change to urine is normal. The patient education materials regarding Valrubicin have been submitted to the patient education department for approval. After updating the bladder instillation protocol and patient education materials, it was determined that an education program and an update to the nursing orientation process were both needed to ensure that nursing staff was knowledgeable about bladder cancer and bladder instillation therapy. Imparting these evidence-based practice changes to staff was essential to ensuring the safety of both staff and their patients as well as improving patient outcomes (See Appendix D).

### **Nursing Education Program**

On February 3, 2015, a program entitled “Urological Surgical Oncology: What Registered Nurses Should Know” was presented to the Urology Clinic staff. The program was an overview of the urological cancers that the nursing staff encounters in their care of their clinic patients. Included in that presentation was a half-hour session focused specifically on bladder cancer discussing diagnosis, types of bladder cancer, treatments for superficial bladder cancer, and safety considerations. Twelve RNs attended the education program. One contact hour of continuing education credit (CE), approved by the Ohio Board of Nursing, was provided to the RNs who attended.

Objectives for the program were to discuss intravesical bladder cancer treatments and safety implications, explain the side effects of intravesical bladder cancer treatments, and discuss potential complications of intravesical bladder cancer treatments. The program was a

lecture utilizing PowerPoint slides, and began with an introduction to bladder cancer.

Statistics and risk factors related to the bladder cancer population were included, as well as the various types of bladder cancer and images of the tumors associated. Pathological staging was discussed including what determines if bladder cancer is superficial or muscle invasive. Procedures and treatment options were presented, with a focus on intravesical therapy. The program then moved to discussing the specifics of BCG, Mitomycin C, and Valrubicin including history of development, indications, side effects of medication, complications, and rare complications. The education program ended with a discussion of the bladder instillation protocol that included specifics on how the procedure is done and safety considerations for nursing staff.

The nursing staff was provided with a participant evaluation form immediately following the education program (see Appendix E). The education program was rated on faculty's expertise facilitating learning, faculty demonstrating respect for the learner's needs (question/opinions), objectives relating to purpose/goals, and the effectiveness of faculty teaching methods (slides, handouts, videos, etc.).

The evaluation form also rated the following: education activity positively impacts care and/or outcomes for patients, did the program support or enhance professional development, list one thing you plan to do differently at work as a result of attending, list other learning needs, and were the objectives of discussing intravesical bladder cancer treatments, safety implications, potential complications, and explaining side effects met. The last question evaluated whether the purpose of the activity was met. Twelve evaluation forms were returned. The responses to the program were overwhelmingly positive. Each of the four evaluation statements were rated by a numerical scale with 5 = strongly agrees, 4 = agrees, 3 =

neutral, 2 = disagree, and 1 = strongly disagrees. For each of the four evaluation statements all twelve participants rated the faculty at a 5 for facilitating learning, demonstrating respect for needs, objectives related to purpose/goals, and teaching methods. The education activity positively impacting care question was answered either yes or no. All twelve respondents indicated that the education activity would positively impact the care of their patients. Some of the respondent's comments for this question included the following:

- More knowledgeable, able to be more supportive of patients
- More in depth information and understanding of care
- My daily work involves the patient population so I am now better informed to take care of this patient population
- Absolutely! The more informative our front line staff are in giving BCG helps to ensure patients have positive outcomes throughout the cancer treatments

The next survey item assessed whether or not the program enhanced the staff's professional development. All twelve respondents answered yes, indicating that the program did enhance their professional development. The next question asked what the responder planned to do differently as a result of the program and responses stated that they now had increased knowledge that would allow them to provide better education for patients, they would continue nursing educational activities, and that they would be more informed to safely care for BCG patients. The next response addressed whether each of the objectives listed at the beginning of the program were addressed and were answered either yes or no. All twelve respondents answered that each of the objectives were met.

The next survey item asked if the purpose of the activity was met, with all respondents answering yes. The final question addressed if there was any bias in the program and all

respondents answered no. The overall feedback from the program was overwhelmingly positive and respondents indicated that their knowledge of bladder cancer, intravesical bladder cancer treatment, and safety considerations were increased as a result of the program. In addition to the education program, changes to the nursing orientation program were developed.

### **Nursing Orientation to the Bladder Intravesical Instillation Clinic**

As newly hired nurses are oriented to the Bladder Intravesical Instillation Clinic, they are informed about the evidence-based protocols with which they will be working. Such information ensures quality and safe care to patients, as well as protection from chemotherapy exposure. The Nursing Orientation Program in the bladder instillation clinic had been in place for years and reflected outdated and inaccurate information. Revisions to the protocol for intravesical therapy for bladder cancer, and updates to patient education materials revealed that the nurse orientation process needed updating. The orientation process was evaluated and compared to current evidence, current practice, and protocol revisions.

### **Competency: Intravesicular Bladder Administration**

When nursing staff begin orientation to the intravesical therapy clinic, they are given a notebook to review that has a variety of materials related to the instillation of BCG, Mitomycin C, and Valrubicin. A completed 'orientation skills' checklist is required before newly hired staff independently administer intravesical bladder therapy. This list was updated in November of 2012 and is entitled "Competency: Intravesicular Chemotherapy BCG (The Ohio State University James Cancer Hospital, 2012).

The list contained two objectives as follows: 1.) RN will demonstrate safe administration of intravesicular chemotherapy according to policy and procedure, and 2.) RN

will describe patient education process, resources, and documentation (The Ohio State University James Cancer Hospital, 2012). The skills check off list was then divided into sections, including review, patient education, and administration. The nursing review section required various nursing journal readings while the patient education section required review of current patient education handouts. The administration section outlined the process for bladder instillation therapy.

To update the form to reflect evidence-based practice, several changes were made (see Appendix F). The title was changed to Competency: Intravesicular Bladder Instillation. Three competency forms were developed specific to each of the three chemotherapeutic agents, including BCG, Mitomycin C, and Valrubicin, because each agent has a unique method for instilling, for patient education priorities, and for side effect profile differences.

The first objective was changed to state the following: RN will demonstrate safe handling and administration of bladder intravesical medications according to policy and procedure. A third objective was added to include the following: RN will recognize side effects and potential serious complications that could result in the deferment of treatment. These changes note the importance of prompt recognition of side effects and potential complications, as treatment decisions are driven by such assessments (Jones & Larchian, 2012).

Nursing staff currently review the article “Intravesical Antineoplastic Therapy Following Transurethral Resection of Bladder Tumors: Nursing Implications for the OR to Discharge” prior to proceeding with orientation (Washburn, 2007). This article is specific to bladder instillation therapy that is given in the OR. Although specific to the OR, the

principles discussed can be applied to the ambulatory setting, and the article will therefore remain as part of the orientation.

An additional article entitled “Bladder Cancer: Current Optimal Intravesical Treatment” has been added to the orientation program to provide additional information on bladder intravesical therapy (Lamm et al., 2005). Another article was added for the nursing staff to review entitled, “Systemic BCG-Osis as a Rare Side Effect of Intravesical BCG Treatment for Superficial Bladder Cancer” (Lukacs, Tschobotko, Szabo, & Symes, 2013). BCG treatment has the potential for serious complications and even death (Lukacs, Tschobotko, Szabo, & Symes, 2013). It is important for the nursing staff to be knowledgeable regarding the potential for serious complications and this article regarding BCGosis will be beneficial in education related to signs and symptoms. The nurses will also review the newly revised bladder instillation protocol, the hospital policy on the safe handling of hazardous drugs, and the Merck TICE® BCG pharmaceutical information.

The nursing staff will review the newly updated patient education handouts regarding BCG, Mitomycin C, and Valrubicin, and will observe an administration of each. The nursing staff will then perform three instillations while observed by experienced nursing staff who assess their accuracy in the use of safety equipment, procedural equipment, and administration. After successfully completing the competency form, the orientees will take a competency quiz (see Appendix G).

The redeveloped competency quiz will test the knowledge of the newly hired nursing staff to ensure that they have the knowledge to safely care for this patient population. The new competency forms and the bladder instillation medication quiz have both been submitted to the clinic nursing educator for approval. The changes to the nursing orientation program

will assist in assuring consistent care utilizing protocol for patients in the bladder instillation clinic.

### **Discussion**

This Cancer Hospital's mission is, "to eradicate cancer from individuals' lives by creating knowledge and integrating groundbreaking research with excellence in education and patient centered care" (OSUMC, 2011, p. 32). The vision of the Cancer Hospital is described as "Creating a cancer free world, one person, one discovery at a time" (OSUMC, 2011, p. 32). Bladder cancer patients are seen in the bladder instillation clinic seeking treatment for their superficial bladder cancer. This project developed due to the need to improve the quality of care for bladder cancer patients. These patients are entitled to receive care that is quality care and is consistent each time they receive their bladder intravesical therapy. Consistent and standardized patient care that is evidence based is essential to the mission and goal of eradicating cancer and creating a cancer free world.

This project was supported by the clinic nursing staff as well as the nurse manager and nursing educator for the clinic. The nursing staff familiar with these treatments acknowledged the need for updated protocols and patient education materials. The nursing staff also expressed a desire for an education program to increase their knowledge to allow them to better care for their patients. The clinic is in the process of moving to a new location, which will necessitate training of newly-hired nurses who will administer intravesical therapy. Updating the orientation process was intended to provide better education and training to the newly hired nursing staff allowing for safer patient care (Lamm et al., 2005). This DNP project provided important improvements to the bladder intravesical instillation clinic's processes, policies, and procedures



### **Bladder Instillation Protocol**

Proposed updates to the bladder instillation protocol were successfully completed and are awaiting approval by nursing leadership. In the future, the evidence-based protocol will provide a consistent level of care based on evidence-based practice as well as optimal patient outcomes (Lamers, Janisse, Brown, Butler, & Watson, 2013). The process of updating the protocol initially proved to be challenging. Upon searching for the protocol, it initially could not be located until a review of the chemotherapy administration protocol revealed it as a subgrouping of content. In reviewing the existing protocol, it was found that there were multiple differences between actual practice and the existing protocol. Care based on an outdated protocol had negative implications for patients as well as the organization, and in order to meet Joint Commission standards, revision was essential.

The other difficulty that was encountered during the process of updating the protocol was the lack of more recent literature discussing the actual procedure of instilling the intravesical therapy. There is a plethora of literature discussing the need for personal safety equipment when instilling hazardous medications. There were articles found that discussed instillation of bladder intravesical medications in the operating room. There were, however, no specific articles dedicated to the instillation of medication in the ambulatory setting.

There were published protocols from other facilities for the patient undergoing bladder intravesical therapy. Studies evaluating the effectiveness of BCG, Mitomycin C, and Valrubicin, while not specifically evaluating the protocol for instillation, did report how the medication was instilled, how often, and side effects noted. The existing protocol was amended based on the available literature and included studies of the effectiveness of BCG in the OR setting as well as other healthcare facilities' intravesicular chemotherapy protocols.

For these amended protocols to be enacted, it is important to have buy-in from all of the stakeholders utilizing the procedure. Stakeholders are organizations, groups, or individuals that have a relationship with an organization and have a stake in the success of a project, process, or organization (Ginter, Duncan, & Swayne, 2013). With any procedural or protocol change, there are a number of stakeholders that are affected. In order to implement a successful change, it is important to identify the stakeholders who could be indirectly or directly affected.

After the updating of the existing protocol, changes were reviewed by both nursing and physician staff. There was overwhelming support for the changes to the protocol. Changes were made based on feedback from the nursing and physician staff to represent best practice. The changes to the protocol necessitated changes to the patient education materials as well.

### **Patient Education Material**

Updates and revisions to patient education materials should represent best practice and ensure that are patients receive sufficient knowledge for self care. Education materials are vital to patients' knowledge of the side effects and complications to observe for, as well as when to seek medical assistance after treatment. Improving patient education can improve understanding of treatments and improve compliance (Kyrtatos, Constandinou, Loizides, & Mumtaz, 2014). Patients reviewing the updated patient education materials stated that the information was easy to read and understand, and the materials are now being evaluated by the patient education department for approval

### **Nursing Education Program**

Improving the quality of patient care starts with nursing personnel having the knowledge to safely care for their patients. *Crossing the Quality Chasm* focused on quality issues and recommended six aims – “care should be safe, effective, patient-centered, timely, efficient and equitable—and 10 rules for care delivery redesign” (IOM, 2013). The DNP is in an excellent position to develop an education program for nursing staff to increase their knowledge of their bladder cancer patient population and treatment. The nursing education program on February 3, 2015 accomplished that objective and was well received by attendees.

The education program allowed for an interactive format with the nursing staff and faculty instructor engaging in a discussion that included case studies and questions. The evaluation responses submitted after the program indicated that the content was successful in offering updated knowledge to improve patient care. The nursing staff indicated that they would be open to attending additional education sessions in the future to continue to increase their knowledge.

### **Nursing Orientation**

The nursing orientation process changes have been proposed to nursing leadership but have yet to be enacted due to.....give reader some idea of timeline or what still has to be done. The changes will improve the knowledge of newly hired nursing staff and apply consistent care to patients, thereby improving patient outcomes. The process to change nursing orientation involved both nursing staff and the nursing educator for the unit. It was important to make changes so that newly hired nursing staff would have the knowledge to safely care for patients.

Poor performance in the care of patients can result from nursing staff not having the knowledge or confidence to care for patients and poor outcomes can result (Lamers, Janisse, Brown, Butler, & Watson, 2013). The current nursing staff and nursing educator reviewed the proposed changes and orientation check off list and approved the changes. The changes have been submitted to nursing leadership for final approval.

### **Conclusions**

Aspects of the bladder instillation clinic protocols, processes, and procedures have needed updating for the past year to reflect evidence based practice and ensure optimal patient outcomes. The process of such updating was daunting at the beginning of this project. Having multiple areas that required updating commanded an immense amount of organization and commitment. The project has been successful in updating the bladder instillation protocol, which is now awaiting approval by nursing leadership before it is implemented. Successful changes were made to update the protocol to reflect the actual practice in the clinic and reflect current evidence-based standards.

A nursing education program was also successfully presented to twelve nurses. The objectives of the program were to increase the nurse's knowledge of bladder cancer, instillation therapy, and side effects and complications of treatment. These objectives were met and the nursing evaluations were positive, indicating that the knowledge that was learned would be applied to patient care and basic practice. Patient education materials were successfully updated to reflect the changes in the bladder instillation protocol. Changes were made to nursing orientation to ensure that nursing staff has the knowledge and skill level needed to successfully instill bladder medications while decreasing the risk of having a traumatic catheter insertion or causing a urinary tract infection. Newly-acquired articles from

nursing journals and other sources will now be required to better educate the nursing staff on bladder intravesical therapy and the medications that are being given.

The nurses will complete a quiz at the end of orientation, as well as annually, to ensure competence. Nurses will also perform three successful bladder instillations prior to being deemed competent to perform on their own. The changes to the nursing orientation program are awaiting approval before they are implemented. Improvements in the bladder instillation protocol, patient education, nursing knowledge, and orientation lead to consistent evidence based care and improved patient outcomes (Lamm et al., 2005).

## Chapter V

### Project Summary

The intravesical bladder instillation clinic in this large cancer hospital in a midwestern city provides care to approximately 450 patients per year. The patients receive either BCG, Mitomycin C, or Valrubicin once a week for either six or three weeks depending on their treatment schedule for their superficial bladder cancer. The instillation of the medication is performed by either the provider or the nursing staff.

Nursing staff must be trained to instill the medication without causing trauma to the urethra or causing a urinary tract infection. Side effects related to the therapy may delay treatment and lengthen recovery. Standardized nursing protocols that are evidence based are essential to quality and safety of these patients. Sufficient nursing knowledge about bladder cancer, the medications instilled as treatments, and the patient teaching required must be provided to outpatient nurses before they are deemed as competent to deliver such care. Yearly updates and evaluations must also be in place to assure that practice is standardized and evidence based.

The current protocol was found to be outdated and not representative of the current practice or literature. Nursing staff were wearing the correct safety equipment (listed in the existing protocol) to give the medication, but the protocol was inaccurate in the equipment that was listed. To update the protocol a search of the literature was done, and evidence was reviewed from nursing journals, textbooks, and other healthcare facilities with published protocols. The current protocol was revised to reflect the current urethral catheters used, the correct nursing safety attire, steps to the procedure, and education to be provided to the

patients. The revised intravesical instillation protocol is awaiting submission to nursing administration for approval.

Patient education needed to be updated as a result of the protocol changes. The BCG patient education handout needed the least amount of changes as it was more recently updated in 2013. The patient's temperature was revised from 101 to 101.5 as a criterion for seeking treatment, and directions for where to seek treatment were revised from the emergency department to a medical professional. The Mitomycin C patient handout had more extensive changes as it had not been updated since 2011. Erroneous information was deleted related to lidocaine being instilled into the urethra and a penile clamp being applied. Information regarding lying flat for fifteen minutes and then getting up to wash was added. The temperature for seeking treatment was increased from 101 to 101.5 degrees Fahrenheit.

Valrubicin did not have any patient education information related to its administration, so a handout was developed utilizing the Mitomycin C template, as both medications are chemotherapies. The information included was specific to Valrubicin. The temperature delineation for seeing treatment was also changed to 101.5 degrees Fahrenheit for the Valrubicin patient information.

### **Future Implications**

This DNP project has been a successful project with the changes made to improve quality of patient care in the bladder intravesical therapy clinic. While positive changes have been made, work remains to further improve the quality of patient care. While the protocol for bladder instillations has been updated, the changes have yet to be presented to nursing administration for review and implementation. Due to the time constraints of this project, there was not enough time to prepare the documentation needed to submit the changes to

nursing administration for approval. After graduation, this DNP student will therefore submit the changes to nursing administration for approval and implementation. Once the necessary approval has been obtained, the protocol will be implemented in the clinic. This information would be beneficial to other institutions. Future publication of nursing implications and protocol development for bladder instillation therapy will be explored.

### **Implications for Nursing Practice and the DNP Essentials**

Advanced practice nursing requires a commitment to the discipline of nursing (AACN, 2006). The role of the DNP is to focus on nursing practice and by translating nursing research into practice. The DNP role is pivotal in effecting patient outcomes and optimizing those outcomes by practicing evidence based care (AACN, 2006). As the practice doctorate in nursing developed, the AACN developed the eight Essentials to guide nursing practice. This DNP project relates directly to several of the DNP Essentials.

The first DNP Essential is the Essential of Scientific Underpinnings for Practice. The DNP graduate needs to be translate research into practice to move the science of nursing forward and improve patient care. This Essential was an integral part of this DNP project. This DNP project utilized the scientific process to improve the protocol for the bladder intravesical instillation. Practice approaches to bladder intravesical therapy were updated to reflect evidence based research. The protocol revision incorporated current evidence, translated research and knowledge into practice, updated practice processes, and will improve patient outcomes in the future.

The second DNP Essential is Organizational and Systems Leadership for Quality Improvement and Systems Thinking (AACN, 2006). Quality improvement is a process that guides advanced practice nurses to achieve best outcomes through best practice. The DNP's



role is to improve the quality and safety of patient care. This DNP project was a quality improvement project with the objective of improving patient care. This DNP project is in the process of being implemented in the bladder intravesical clinic. The protocol revision, updated patient education handouts, and progressive orientation program will provide patients with consistent and quality care.

The care provided by the nursing staff will be safer and improves the quality of patient care for patients. Leadership is also an important component of this Essential in addition to quality improvement. Leadership and teamwork skills were needed in working with nursing and physician team members to ensure that changes to the program were representative of the current evidence available.

The sixth Essential is Interprofessional Collaboration for Improving Patient and Population Health Outcomes (AACN, 2006). Collaborative efforts and an interdisciplinary approach were implemented to achieve and implement these program revisions. Communication was important in evaluating the changes needed to improve patient care. In order to improve outcomes for this population, the staff of the bladder intravesical clinic collaborated to evaluate the proposed changes. Feedback from the nursing staff, the nursing educator, and physicians was obtained prior to submission to the organization's management for approval of the changes. Teamwork increases the quality of care for all patient population.

Essential Eight is the last Essential addressed in this DNP, which is Advanced Practice Nursing (AACN, 2006). Advanced practice nursing provides leadership to nursing staff in the clinics. The advanced practice nurse is in a position to share knowledge with nursing as well as other disciplines. This DNP project focused, in part, on development of a nursing education program utilizing lecture, discussion, and a PowerPoint presentation for nursing

staff. Nursing staff were presented with information regarding bladder cancer and treatment with intravesical therapy. The plan is for nurses to implement the use of this new knowledge by translating it into improved quality of care and outcomes for patients.

### **Conclusion**

Healthcare quality is of profound importance in hospitals, nursing facilities, and outpatient settings. Medical errors can cause morbidity and mortality, with estimates of between 44,000 and 98,000 deaths annually related to those errors (IOM, 2009). Many more patients suffer preventable injuries. Methods to facilitate safety and quality include established protocols, which provide a standardized approach to procedures. Nursing orientations that are updated and evidence based serve to increase nursing knowledge and decrease medical errors. A consistent and standardized protocol for implementing treatments will facilitate patient outcomes (Bashford & Shaffer, 2012).

This project is an important quality improvement project utilizing the Iowa model to improve patient care in the bladder intravesical instillation clinic at a cancer hospital outpatient facility. Implementation of this project has contributed to evidence-based practice change, high quality patient care, and optimal patient outcomes. This DNP project improves patient outcomes through evidence-based practice and provides nursing staff with the training and knowledge to provide excellent and safe nursing care.

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## Appendix A

***NOTE: Bold and Italicized Font highlights changes made from existing protocol.***

Effective Date: 07/2002

Last Review Date: 08/2013 (amended 3/2015)

Approval Signature on file: \_\_\_\_\_

## DIVISION OF NURSING SERVICES

### PATIENT CARE STANDARDS OF PRACTICE ■

Policy ■ Procedure ■ Protocol □ Guideline

**TITLE:** BACILLUS CALMETTE-GUERIN (BCG) and CHEMOTHERAPEUTIC AGENTS, ADMINISTRATION OF and CARE OF THE PATIENT RECEIVING THIS BLADDER INTRAVESICAL THERAPY

#### DEFINITIONS:

- 1) **Immunotherapy** - Type of biotherapy. Mechanism of action is stimulation of immune system. BCG is a type of Immunotherapy.
- 2) **Chemotherapy: Prevention or treatment of a disease by chemical agents. Mitomycin C and Valrubicin are types of chemotherapy.**
- 3) **Hazardous Drug:** Link to Nursing Guideline: Hazardous Drugs, Safe Handling  
Link to Pharmacy: Hazardous Drugs

#### POLICY STATEMENTS:

1. Registered Nurses (RNs) who have demonstrated knowledge and skill in administration of **BCG/Chemotherapy** may administer chemotherapy/biotherapy agents.
2. The RN administering BCG/chemotherapy agents will review the five rights of drug administration prior to chemotherapy /biotherapy administration.  
**5 Rights:**
  - a) Right Patient
  - b) Right Medication
  - c) Right Dose
  - d) Right Route
  - e) Right Time
(Mosby's Nursing Skills lists a sixth right as being the "**Right Documentation**".) See statement # 6 below.
3. The RN administering **BCG/chemotherapy** will practice safe handling techniques to ensure optimal safety for the patient and all staff that come into contact with the patient and his/her environment.
4. The RN will develop an individualized teaching plan for patients receiving **BCG/chemotherapy**.
5. The RN administering **BCG/chemotherapy** will review the BCG/chemotherapy administration procedure with the patient / family prior to administration.

6. The RN will document **BCG/chemotherapy** administration as outlined in this policy.
7. The RN administering **BCG/chemotherapy** will administer or assess the need for medications to prevent or minimize anticipated reactions and will monitor effectiveness to determine if additional symptom management is needed.
8. NO verbal orders will be taken for **BCG/chemotherapy**.
9. **BCG/Chemotherapy** for bladder cancer is considered a high-risk medication. Follow guidelines as directed in the “Administration of High Risk Medications” Policy.

#### **SUBTITLE: A. PREPARATION FOR BCG/CHEMOTHERAPY ADMINISTRATION**

##### **PROCEDURAL STATEMENT:**

*The RN assesses the patient’s physical and psychological readiness for BCG/chemotherapy bladder intravesical administration. The RN will become familiar with the BCG/chemotherapy pharmacology: mechanism of action, usual dosage, route of administration, acute and long-term effects, and route of excretion.*

##### **PROCEDURES:**

1. Prior to **BCG/chemotherapy** administration, the nurse should conduct a pretreatment patient assessment that provides data in the following areas:
  - a. Past medical history relevant to planned treatment (i.e., drug allergy, cardiac, pulmonary, or renal disease(s), previous radiation, past surgeries, etc.). Consider comorbidities, particularly with elderly patients.
  - b. Previous experience with **BCG/chemotherapy** treatment including types of drugs administered, physical and emotional adverse reactions, and interventions employed successfully to alleviate side effects.
  - c. *Treatment specific, head to toe assessment including reviewing the Quantitative Symptom Score Sheet for hematuria and treatment side effects.*
  - d. Obtain and document current and accurate height and weight in stocking feet.
  - e. Patient / family knowledge and learning needs relevant to regimen, desire for information, and motivation and readiness to learn. Reinforce, clarify, and/or supplement information provided by the physician.
  - f. Patient / family anxiety level related to treatment and their coping methods.
  - g. Patient and / or family’s ability to manage the patient’s post-treatment care in the home.
  - h. Available home and community resources with referral to appropriate agencies as needed. (Communicate needs to PCRM, Social Worker, CNP, or CNS as appropriate)
2. Reviewing of treatment orders:
  - a. Prior to administration, the nurse must review the attending physician endorsed orders.
    - 1) Review of Orders: The nurse will review the orders in IHIS. If questions arise when checking the **BCG/chemotherapy order**, the nurse should call the attending physician or pharmacist to seek clarification.
    - a) *Other resources to clarify BCG/chemotherapy orders may include:*
      - **Nurse Practitioner (NP)**
      - **Physician Assistant (PA)**

- b) The *BCG/Chemotherapy order set* should provide clear communication regarding:
  - i. *Number of doses/weeks BCG/chemotherapy is to be instilled*
  - ii. *Time doses are to be given*
  - iii. *Pre-medications to be given with BCG/chemotherapy regimen (if any).*

3. BCG/Chemotherapy Checks:

- a. *Prior to administering BCG/chemotherapy:*
  - 1) *Independent Double Check Procedure: Two RN's independently compare the medication in hand against the order to ensure administration of the correct drug, the correct patient, using patient name and medical record number, at the correct dose, and correct rate (if applicable), given by the correct route, and at the scheduled time. This includes verification of current height, weight, and BSA.*
  - 2) *The RN(s) independent double checks will be documented in IHIS.*
- b. *At the beginning of each shift:*
  - 1) *The RN caring for the patient will verify the dose is correct and document this verification on the medication administration record in IHIS*
- c. *Missing Dose:*
  - 1) *If you are unable to locate a dose of BCG/chemotherapy and /or if you are unsure if a dose has been administered, then check documentation, contact pharmacist, and/or contact previous shift RN.*

*OUTCOME: The patient will receive the prescribed BCG/chemotherapy in a safe and appropriate manner with minimal adverse reaction.*

**SUBTITLE: B. SAFE HANDLING OF HAZARDOUS DRUGS**

**\*For procedural information related to cleaning up a BCG/Chemotherapy spill:**

**POLICY STATEMENTS:**

- 1. Nursing staff who administer or care for patients receiving hazardous drugs (e.g. antineoplastic and cytotoxic drugs) and / or investigational agents need to be knowledgeable about, and maintain safe handling techniques. These techniques are designed to protect nurses and others from potential risks associated with exposure to hazardous drugs. Pharmacy will determine when an investigational drug requires special handling and label accordingly with an "Antineoplastic Material, Handle Properly" or "Medication Exposure Precautions" label.
- 2. Reduce the risk of contamination by prohibiting staff from eating, drinking, applying cosmetics, or storing foods in areas where hazardous drugs are prepared or administered.

**INTRAVESICULAR BLADDER INSTILLATION****GENERAL GUIDELINES / INFORMATION**

1. Used to treat bladder cancer providing direct exposure of nonmuscle invasive tumors of the bladder to an immunotherapeutic drug, BCG, and chemotherapeutic drugs such as thiotepa, mitomycin, epirubicin, doxorubicin, valrubicin, and mitoxantrone.
2. Requires placement of a **urethral** catheter
3. Nursing implications:
  - a) Maintain sterile technique for **catheter insertion**
  - b) ***Follow physician orders or protocol for scheduling or re-positioning the patient and leaving a Foley catheter in place after instilling the BCG/chemotherapy***
  - c) Wear appropriate PPE
  - d) Suspect extravasation for pain not relieved with pain medication following vesicant administration. Release the agent and urine and notify physician immediately
4. Potential complications include:
  - a) Urinary tract infection
  - b) Cystitis
  - c) Bladder contracture
  - d) Urinary urgency
  - e) Flu-like symptoms (following Bacillus Calmette-Guerin [BCG] administration)
  - f) Potential extravasation of vesicant agents; can result in peritoneal necrosis, fistula formation, and chronic pain

**PROTOCOL:**

TOPIC	IMPLEMENTATION	FREQUENCY
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<b>List of supplies and equipment</b>	<ul style="list-style-type: none"> <li>• <b>Urethral catheter kit (without catheter)</b></li> <li>• Sterile gloves</li> <li>• <b>14 or 16 French-Coude or red rubber catheter</b></li> <li>• CHUX® (1)</li> <li>• <b>Chemotherapy gloves</b></li> <li>• Protective plastic gown (1)</li> <li>• Medication as prepared per Pharmacist</li> <li>• <b>Biohazard bag (Red for BCG or Yellow for Mitomycin/Valrubicin)</b></li> <li>• Exam table</li> <li>• <b>Blanket</b></li> <li>• Peri-pad for patient post procedure</li> </ul>	
<b>Patient/Family Education Materials Available</b>	<ul style="list-style-type: none"> <li>• Bladder Irrigation Treatment for Bladder Cancer</li> <li>• BCG Therapy – Intravesical Treatment for Bladder Cancer</li> <li>• Mitomycin – C Therapy Intravesical Treatment for Bladder Cancer</li> <li>• <b>Valrubicin (Valstar) Therapy Intravesical Treatment for Bladder Cancer</b></li> </ul>	
<b>Patient Education</b>	1. Explain the procedure, its risks, benefits, and after procedure self-care instructions.	Before procedure
	2. Review patient education materials (as listed above) with the patient.	Before procedure

TOPIC	IMPLEMENTATION	FREQUENCY
<b>Patient Education (cont.)</b>	3. Explain to patient - the procedure will be done once per week for <b>either three or six weeks in a row.</b>	Before procedure

4. Explain to patient – maintain a normal fluid intake; do not force fluids before the procedure.	Before procedure
5. Explain to patient NOT to urinate for 2 hours after the procedure. ( <b>BCG needs to remain in the bladder for 2 hours but not more than 3 hours</b> )	Before and post procedure
6. Instruct patient to VOID seated on commode for all VOIDS 6 hours after procedure and to use same toilet every time.	Before and post procedure
7. With the BCG treatment, have patient disinfect the voided urine in the toilet with an equal volume or 1 cup of household bleach to the urine and <b>let it stand for 15 minutes before flushing the toilet twice with the toilet lid down</b> . This should be done with every void for 6 hours after the procedure.	Before and post procedure
8. Instruct patient to increase fluids beginning 2 hours after procedure to “flush” the bladder.	Before procedure
9. Encourage good hand washing technique after each void following procedure. <b>Instruct the patient to wash with gentle soap and water</b> . This medication can irritate skin on hands and genitals.	
10. Explain possible procedure side effects and complications.	Before procedure



	11 . <i>Instruct patient to seek medical attention if they have a fever over 101.5 that does not resolve with Tylenol or NSAIDs after two hours or anything else they find bothersome.</i>	Post procedure
TOPIC	IMPLEMENTATION	FREQUENCY
Procedure Specific Assessment Interventions	<p>1. <i>Obtain vital signs.</i></p> <p>2. <i>Assess patient for symptoms of urinary tract infection, i.e., temperature greater than 101.5 °; chills, pain or burning with urination, hematuria with or without clots, urinary frequency, urge to urinate- but unable to urinate, cloudy or foul smelling urine, low back or abdominal pain, nausea/vomiting, skin rash or joint pain.</i></p>	Before procedure

<p>There are three intravesical medications:</p> <ul style="list-style-type: none"> <li>A. <i>Mitomycin C (chemotherapy) prepared in a 60 ml catheter syringe enclosed in a light sensitive bag. Catheter adapter will come with the syringe.</i></li> <li>B. <i>Valrubicin (Valstar) (chemotherapy) prepared in a 75 ML infusion bag enclosed placed in a light sensitive bag. Tubing will come with the vial.</i></li> <li>C. <i>BCG (live bacteria) in a vial with a rubber stopper placed in a light sensitive bag. Tubing will come with the vial.</i></li> </ul>	
5. Obtain and set up equipment / supplies for the procedure.	
6. Have patient remove clothing from the waist down. Have patient sit on a protective plastic barrier on the table and <b>cover with a blanket</b> . Assist patient to a supine position prior to procedure.	
<b>7. Obtain physician order for Lidocaine 2% Uro-Jet, if indicated, and instill into urethra prior to catheterization.</b>	Before procedure
<b>8. Insert 14 or 16 Coude or red rubber catheter. Allow urine to drain into sterile container and discard contents. Verify non-traumatic catheterization by return of clear yellow urine.</b>	During procedure
<b>9. PPE (mask, goggles, gloves (chemo and sterile), and fluid resistant gown) will be worn from start to finish of procedure.</b>	Entire procedure

TOPIC	IMPLEMENTATION	FREQUENCY
Procedure Specific Assessment Interventions (cont.)	<p>10. <b>Medication Installation (Physician, Certified Nursing Practitioner, Physician Assistant and/or RN)</b></p> <p>A. <b><u>Mitomycin C:</u></b> The medicine comes prepared in a 60 ml toomey syringe. Insert urethral catheter in patient. Instill medicine into urethral catheter by slow injecting the medication into the bladder. Remove the ureteral catheter. Place all items exposed to medicine in a yellow biohazard bag. Place bag in yellow chemo waste container.</p> <p>B. <b><u>BCG:</u></b> Medicine comes from pharmacy in a vial with a rubber stopper with special tubing for access (BCG Instillation Set). Attach pointed end of tubing into rubber stopper. Attach other end of tubing into end of urethral catheter. Hold the vial of BCG upside down and squeeze the bottle to start the flow of medication down the tubing. Allow medicine to drain into bladder by gravity. Remove the urethral catheter. Place all items exposed to medicine in a red biohazard bag. Place bag in a red biohazard waste container.</p> <p>C. <b><u>Valrubicin:</u></b> The medicine comes prepared in a 75 ml instillation bag. Insert urethral catheter in patient. Instill medicine into urethral catheter by slowly releasing the clamp to allow the medication to instill by gravity into the bladder. Remove the urethral catheter. Place all items exposed to medicine in a yellow biohazard bag. Place bag in yellow chemo waste container.</p>	During procedure

	<b><i>11. Patient should not void for 2 hours post procedure.</i></b>	Post Procedure
<b>Post Procedure Complications Signs/Symptoms</b>	<p><b><i>1. Have patient watch for any signs and symptoms of infection, such as fever, chills, malaise, and flu-like symptoms. Notify physician if fever greater than 101.5° and does not resolve after 2 hours with Tylenol or NSAIDs, or go to the nearest Emergency Room.</i></b></p> <p><b><i>2. It is normal to have burning with urination, urinary frequency, and urinary urgency after the procedure. Note any burning with urination that persists beyond three to five days post procedure.</i></b></p>	Post procedure

## Appendix B

***NOTE: Bold and italicized font notes changes made from existing handout..***

### PATIENT EDUCATION

## BCG Therapy - Intravesical Treatment for Bladder Cancer

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Your doctor has recommended that you be treated with Bacillus Calmette-Guerin (BCG) Therapy. BCG is an **intravesical** therapy. Intravesical is when a liquid treatment is placed into the bladder through a catheter or tube. BCG is the best treatment for your type of bladder cancer. It is a live Tuberculosis (TB) vaccine which has been weakened to reduce the risk of infection. This will help your body's immune system to fight the cancer cells. BCG lowers the chance that cancer will return or continue to grow. This treatment is well tolerated and is safe. This treatment is usually given once a week for six weeks. ***Alternately, it can be given once a week for three weeks if receiving maintenance therapy.***

### Before Your Treatment

- **Do not** drink anything for 4 hours before treatment.
- Empty your bladder right before the treatment.
- You will be given a form called, the Quantitative Symptom Score Sheet.
- On the day of your first treatment, you will fill in the Pre-Treatment column on the form. Your nurse will help you fill out this information.
- Bring your Quantitative Symptom Score Sheet with you to each visit. Make sure to fill it out around the same time each day. Your nurse will discuss your answers with you before your treatment.

### On the Day of Your Treatment

- You will be asked to undress from the waist down and given a sheet to cover yourself.

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**This handout is for informational purposes only. Talk with your doctor or health care team if you have any questions about your care.**

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- Your nurse will have you lie on your back on the exam table.
- A cleansing solution called Betadine will be used to lower the risk of infection from the catheter placement.
- Lidocaine gel, a numbing medicine, will be placed into your urethra to make the catheter placement more comfortable. The urethra is the tube that carries urine out of your body.
- The catheter will be placed into your urethra.
- This catheter will let the urine drain from the bladder. Once the urine is drained, BCG will be placed into your bladder through the same catheter.
- After the BCG is given, the catheter is removed. The BCG will remain in your bladder. You will need to lie flat for 15 minutes after the procedure.
- After lying flat, you will then be able to get dressed. You will need to wear a pad home to soak up any liquid that may leak out.

### After Your Treatment

- **Do not** drink anything for 2 hours after your treatment.
- To keep the BCG in your bladder, do not urinate for 2 hours if possible. However, do not hold your urine for longer than 3 hours.
- Write down how long you held the medicine in your bladder on the bottom of your Quantitative Symptom Score Sheet. Your nurse will ask you for this information at each visit. You may return to your normal activities.

### Safety Precautions

- **Use the same toilet** in your home each time you urinate.
- To avoid splashing or spraying, **sit on the toilet while you urinate**.
- **During the first 6 hours after treatment, follow these steps each time you urinate:**
  - ▶ **Do not flush the toilet** when you finish urinating.
  - ▶ **Before you flush**, you must first pour 1 cup of bleach into the toilet, and let it sit for 15 minutes. You *should then close the lid and flush the toilet two times*.

### BCG Therapy - Intravesical Treatment for Bladder Cancer

- ▶ Wash your hands and genital area with soap and water after each time you urinate to avoid skin irritation.
- ▶ Any clothes or linens that have urine on them should be washed on the hot cycle in a washing machine. Wash soiled laundry separately.
- ▶ If urine splashes or spills on the floor, toilet seat or other areas clean it up with a water and bleach mixture (1/2 cup bleach and 4 cups of water).
- **If you are sexually active you or your partner must wear a condom:**
  - ▶ During your 6 weeks of treatment
  - ▶ And for 1 week after your last treatment

### Side Effects

**These symptoms usually do not last longer than 3 to 5 days.** There are medicines that can reduce side effects. Tell your doctor or nurse if you have any of the following:

- Fever
- Frequent urination
- Urgency of urination
- Blood in urine
- Burning while urinating
- Bladder spasms or pain
- Arthritic or joint pain
- Flu-like symptoms

***If you have a temperature greater than 101.5 degrees Fahrenheit that does not resolve within two hours after taking Tylenol or Ibuprofen, seek medical attention.***

**BCG Therapy - Intravesical Treatment for Bladder Cancer**

## Appendix C

***NOTE: Bold and italicized font notes changes made from existing handout.***

## PATIENT EDUCATION

## Mitomycin-C Therapy Intravesical Treatment for Bladder Cancer

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Your doctor has recommended that you be treated with Mitomycin-C therapy. Mitomycin-C is an **intravesical** therapy. Intravesical is when a liquid treatment is placed into the bladder through a catheter or tube. Mitomycin-C is the best treatment for your type of bladder cancer.

It lowers the chance that the cancer will return or continue to grow. Mitomycin-C is a chemotherapy drug. However, because it is given through the bladder, it does not usually have the same side effects as chemotherapy given through an IV. This treatment is well tolerated and is safe. This treatment is usually given once a week for six weeks.

### Before Your Treatment

- **Do not** drink anything for 4 hours before treatment.
- Empty your bladder right before the treatment.
- You will be given a form, called the Quantitative Symptom Score Sheet.
- On the day of your first treatment, you will fill in the Pre-Treatment column on the form. Your nurse will help you fill out this information.
- Bring your Quantitative Symptom Score Sheet with you to each visit. Make sure to fill it out around the same time each day. Your nurse will discuss your answers with you before your treatment.

### On the Day of Your Treatment

- You will be asked to undress from the waist down and given a sheet to cover yourself.
- Your nurse will have you lie on your back on the exam table.

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- A cleansing solution called Betadine will be used to lower the risk of infection from the catheter placement.
- Lidocaine gel, a numbing medicine, will be placed into your urethra to make the catheter placement more comfortable. The urethra is the tube that carries urine out of your body.
- The catheter will be placed into your urethra.
- This catheter will let the urine drain from the bladder. Once the urine is drained, Mitomycin-C will be placed into your bladder through the same catheter.
- ***After the Mitomycin-C is given, the catheter is removed. The Mitomycin-C will remain in the bladder. You will need to lie flat for 15 minutes after the procedure. After lying flat for 15 minutes, you will be able to get up, wash your genital area, and get dressed. You will need to wear a pad home to soak up any liquid that may leak out.***

### After Your Treatment

- **Do not** drink anything for 2 hours after your treatment.
- ***Try to keep the Mitomycin-C in your bladder and do not urinate for 2 hours if possible. However, do not hold your urine for longer than 3 hours.***
- ***Write down how long you held the medicine in your bladder on your Quantitative Symptom Score Sheet. Your nurse will ask you for this information at each visit.***
- You may return to your normal activities.

### Safety Guidelines

- **Use the same toilet** in your home each time you urinate.
- To avoid splashing or spraying, **sit on the toilet while you urinate.**
- **During the first 6 hours after treatment, follow these steps each time you urinate:**
  - ▶ ***After urinating, flush the toilet twice with the toilet lid down.***
  - ▶ ***Wash your genital area after you urinate to avoid skin irritation.***
- **If you are sexually active you or your partner must wear a condom:**
  - ▶ During your 6 weeks of treatment
  - ▶ And for 1 week after your last treatment

### Side Effects

**These symptoms usually do not last longer than 3 to 5 days.** There are medicines that can reduce side effects. Tell your doctor or nurse if you have any of the following:

- Fever
- Frequent urination
- Urgency of urination
- Blood in urine
- Burning while urinating
- Bladder spasms or pain

***If you have a temperature greater than 101.5 degrees Fahrenheit that does not resolve within two hours after taking Tylenol or Ibuprofen, seek medical attention.***

## Appendix D

*NOTE: This is a newly developed patient education handout.*

### PATIENT EDUCATION

# Valrubicin (Valstar) Therapy Intravesical Treatment for Bladder Cancer

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Your doctor has recommended that you be treated with Valrubicin therapy. Valrubicin is an **intravesical** therapy. Intravesical is when a liquid treatment is placed into the bladder through a catheter or tube. Valrubicin is the best treatment for your type of bladder cancer.

It lowers the chance that the cancer will return or continue to grow. Valrubicin is a chemotherapy drug. However, because it is given through the bladder, it does not usually have the same side effects as chemotherapy given through an IV. This treatment is well tolerated and is safe. This treatment is usually given once a week for six weeks.

### Before Your Treatment

- **Do not** drink anything for 4 hours before treatment.
- Empty your bladder right before the treatment.
- You will be given a form, called the Quantitative Symptom Score Sheet.
- On the day of your first treatment, you will fill in the Pre-Treatment column on the form. Your nurse will help you fill out this information.
- Bring your Quantitative Symptom Score Sheet with you to each visit. Make sure to fill it out around the same time each day. Your nurse will discuss your answers with you before your treatment.

### On the Day of Your Treatment

- You will be asked to undress from the waist down and given a sheet to cover yourself.
- Your nurse will have you lie on your back on the exam table.

---

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- A cleansing solution called Betadine will be used to lower the risk of infection from the catheter placement.
- Lidocaine gel, a numbing medicine, will be placed into your urethra to make the catheter placement more comfortable. The urethra is the tube that carries urine out of your body.
- The catheter will be placed into your urethra.
- This catheter will let the urine drain from the bladder. Once the urine is drained, Valrubicin will be placed into your bladder through the same catheter.
- After the Valrubicin is given, the catheter is removed. The Valrubicin will remain in the bladder. You will need to lie flat for 15 minutes after the procedure. After lying flat for 15 minutes, you will be able to get up, wash your genital area, and get dressed. You will need to wear a pad home to soak up any liquid that may leak out.

### After Your Treatment

- **Do not** drink anything for 2 hours after your treatment.
- Try to keep the Valrubicin in your bladder; do not urinate for 2 hours if possible. However, do not hold your urine for longer than 3 hours.
- Write down how long you held the medicine in your bladder on your Quantitative Symptom Score Sheet. Your nurse will ask you for this information at each visit.
- You may return to your normal activities.

### Safety Guidelines

- **Use the same toilet** in your home each time you urinate.
- To avoid splashing or spraying, **sit on the toilet while you urinate.**
- **During the first 6 hours after treatment, follow these steps each time you urinate:**
  - ▶ **After urinating**, flush the toilet twice with the toilet lid down.
  - ▶ Wash your genital area after you urinate to avoid skin irritation.
- **If you are sexually active you or your partner must wear a condom:**
  - ▶ During your 6 weeks of treatment
  - ▶ And for 1 week after your last treatment

### Side Effects

**These symptoms usually do not last longer than 3 to 5 days.** There are medicines that can reduce side effects. Tell your doctor or nurse if you have any of the following: Fever

- Frequent urination
- Urgency of urination
- Blood in urine
- Burning while urinating
- Bladder spasms or pain

**If you have a temperature greater than 101.5 degrees Fahrenheit that does not resolve within two hours after taking Tylenol or Ibuprofen, seek medical attention.**

**Appendix E**

**Hospital Division of Nursing**  
**Competency: Intravesical Bladder Therapy Administration**

Name \_\_\_\_\_

Date \_\_\_\_\_

<b>Objectives</b>			
1. RN will demonstrate safe handling and administration of bladder intravesical medications according to policy and procedure. 2. RN will describe patient education process, resources, and documentation. 3. RN will recognize side effects and potential serious complications that could result in deferment of treatment.			
Components	Evaluation	Date	Evaluator Signature Participant Signature (if self study)
<ul style="list-style-type: none"> <li>• Review               <ol style="list-style-type: none"> <li>1. James Policy: Chemotherapeutic &amp; Biotherapeutic Agents, Administration of and Care of the Patient Receiving this Therapy</li> <li>2. James policy: Hazardous Drugs, Safe Handling</li> <li>3. TICE BCG pharmaceutical drug insert (Merck, 2013)</li> <li>4. Literature: Bladder Cancer: Current Optimal</li> <li>5. Intravesical Treatment (Lamm, McGee, Hale, 2005)</li> <li>6. Systemic BCG-Osis as a Rare Side Effect of Intravesical BCG Treatment for Superficial Bladder Cancer (Lukacs, Tschobotko, Szabo, &amp; Symes, 2013)</li> </ol> </li> </ul>	Yes      No		
<ul style="list-style-type: none"> <li>• Patient Education               <ol style="list-style-type: none"> <li>1. Review James Patient Education: BCG</li> </ol> </li> </ul>	Yes      No		

Therapy – Intravesical Treatment for Bladder Cancer, Mitomycin-C Therapy Intravesical Treatment for Bladder Cancer, and Valrubicin Therapy for Bladder Cancer 2. Describes appropriate patient education, resources, and EMR documentation	Met	Unmet		
• Complete written case study with score of at least 80%	Yes	No		
• Administration <ol style="list-style-type: none"> <li>1. Verbalizes parameters to evaluate prior to administration</li> <li>2. Verbalizes correct management of side effects and complications</li> <li>3. Demonstrates intravascular bladder therapy administration according to policy and procedure</li> <li>4. Describes appropriate documentation of procedure.</li> </ol>	Met	Unmet		
	Met	Unmet		
Resources used to develop education: James Policy: Chemotherapeutic & Biotherapeutic Agents, Administration of and Care of the Patient Receiving this Therapy & Hazardous Drugs, Safe Handling, TICE BCG pharmaceutical drug insert (Merck, 2009), Nursing Implications from the OR to Discharge (Washburn, 2007), Systemic BCG-Osis as a Rare Side Effect of Intravesical BCG Treatment for Superficial Bladder Cancer (Lukacs, Tschobotko, Szabo, & Symes, 2013), James Patient Education: BCG Therapy – Intravesical Treatment for Bladder Cancer, Mitomycin-C Therapy Intravesical Treatment for Bladder Cancer, and Valrubicin Therapy for Bladder Cancer				

**Hospital Division of Nursing**  
**Competency: Intravesical Bladder Therapy Administration**  
**BCG Competence Checklist**

**Skill: Intravesical Bladder Therapy Administration: BCG**

**Name**\_\_\_\_\_

**Date**\_\_\_\_\_

<b>Critical Elements</b>	<b>Met</b>	<b>Not Met</b>	<b>N/A</b>	<b>Comments</b>
Completed written quiz with a grade of at least 80%.				
Verbalizes parameters to evaluate prior to BCG administration				
Observes three BCG bladder instillations				
Demonstrates three intravesical BCG bladder instillations according to policy and procedure				
Verbalizes correct management of BCG side effects and complications				

☐ Satisfactory      ☐ Unsatisfactory

Name and Title of Evaluator\_\_\_\_\_

**Hospital Division of Nursing**  
**Competency: Intravesical Bladder Therapy Administration**  
**Mitomycin C Competence Checklist**

**Skill: Intravesical Bladder Therapy Administration: Mitomycin C (MMC)**

Name\_\_\_\_\_

Date\_\_\_\_\_

Critical Elements	Met	Not Met	N/A	Comments
Completed written quiz with a grade of at least 80%.				
Verbalizes parameters to evaluate prior to MMC administration				
Observes three MMC bladder instillations				
Demonstrates three intravesical MMC bladder instillations according to policy and procedure				
Verbalizes correct management of MMC side effects and complications				

☐ Satisfactory      ☐ Unsatisfactory

Name and Title of Evaluator\_\_\_\_\_

**Hospital Division of Nursing  
Competency: Intravesical Bladder Therapy Administration  
Valrubicin Competence Checklist**

**Skill: Intravesical Bladder Therapy Administration: Valrubicin (Valstar)**

**Name** \_\_\_\_\_

**Date** \_\_\_\_\_

<b>Critical Elements</b>	<b>Met</b>	<b>Not Met</b>	<b>N/A</b>	<b>Comments</b>
Completed written quiz with a grade of at least 80%.				
Verbalizes parameters to evaluate prior to Valstar administration				
Observes three Valstar bladder instillations				
Demonstrates three intravesical Valstar bladder instillations according to policy and procedure				
Verbalizes correct management of Valstar side effects and complications				

☐ Satisfactory      ☐ Unsatisfactory

**Name and Title of Evaluator** \_\_\_\_\_



**Appendix F**  
**Intravesical Bladder Therapy Administration Quiz**

Name\_\_\_\_\_

Date\_\_\_\_\_

1. What are the three types of intravesical medications used in the BCG clinic for superficial bladder cancer?
  - a. \_\_\_\_\_
  - b. \_\_\_\_\_
  - c. \_\_\_\_\_
  
2. What are the most common size and types of urethral catheters used for instilling intravesical bladder medications into a male and female patient's bladders?
  - a. \_\_\_\_\_
  - b. \_\_\_\_\_
  
3. A patient presents to the clinic for his bladder instillation therapy. He is complaining of severe dysuria, increased urinary frequency and urgency, and hematuria since his last treatment. The nurse will discuss the symptoms with the provider but orders the BCG from pharmacy knowing that treatment will probably proceed as scheduled.
  - a. True or False
  
4. Upon inserting the urethral catheter into the bladder, the nurse notices there is a moderate amount of hematuria. What is the nurse's next step?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
  
5. The nurse is educating a new patient on side effects that they may experience. What temperature should the patient be counseled to seek medical attention or call their provider for?  
\_\_\_\_\_

6. Name two side effects a patient may experience as a result of bladder intravesical therapy.
- \_\_\_\_\_
  - \_\_\_\_\_
7. BCGosis can be a life threatening complication of BCG instillation therapy. What causes BCGosis?
- \_\_\_\_\_
8. List three symptoms of BCGosis.
- \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
9. How long should a patient be instructed to hold the intravesical medication in his/her bladder?
- \_\_\_\_\_
10. What safety equipment should a nurse wear to protect themselves from exposure to biohazardous medications such as BCG, Mitomycin C and Valrubicin?
- \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
  - \_\_\_\_\_
11. Would the nurse educate the patient to expect possible flu like symptoms of fever and body aches with Mitomycin C instillation therapy?
- True or False?
12. What are two Irritative voiding side effects a patient may experience when receiving Mitomycin C or Valrubicin intravesical instillation therapy?
- \_\_\_\_\_
  - \_\_\_\_\_
13. BCG can be given in either an induction course or a maintenance course. How many doses does a patient receive with each treatment?
- \_\_\_\_\_
  - \_\_\_\_\_

**14.** What is the standard dose used at the James for BCG, MMC, and Valrubicin?

- a. \_\_\_\_\_
- b. \_\_\_\_\_
- c. \_\_\_\_\_

**15.** Holding intravesical bladder instillation medication longer than two to three hours will not increase a patient's side effects.

- a. True or False